REMARKS

Previously, claims 1-7 were all the claims pending in the application. Claims 4-6 are withdrawn.

Upon entry of the amendment, which is respectfully requested, claims 1, 2, 3, and 7 will be amended, and new claims 8 and 9 will be added. Support for the claim amendments and new claims can be found throughout the specification and originally filed claims.

Specifically, claim 1 is to recite "isolated bacterial flagellins." Support for this amendment can be found at least in paragraph [22] at page 4.

Claims 2 and 3 are amended to correct typographical errors. Claim 7 is amended to delete its dependency to non-elected claim 6 and specific diseases against which the recited vaccines work.

New claims 8 and 9 are introduced to recite the specific diseases, such as tetanus toxoid, cholera, typhoid fever, influenza, SARS, and uterine cervical cancer, against which the recited vaccines work. Support for the new claims can be found at least in original claim 7.

Additionally, Specification is amendment to correct a typographical error.

Accordingly, no new matter has been introduced.

I. Preliminary Matter

A. Applicants thank the Examiner for acknowledging Applicant's claim to priority and receipt of the priority document. *See* Page 2, Office Action of February 2, 2009.

B. Applicants also thank the Examiner for acknowledging receipt and acceptance of the drawings filed. *See* Page 2, Office Action of February 2, 2009.

It appears, however, that the Examiner inadvertently did not acknowledge Applicant's claim to priority, receipt of the priority document, receipt and acceptance of the drawings in the Office Action Summary. Applicants respectfully request that the Examiner indicate the above acknowledgements in the Summary as well in a next Office Action.

C. Applicants thank the Examiner for returning a signed and initialed copy of the PTO Forms SB/08 that accompanied the Information Disclosure Statements filed July 11, 2006, July 19, 2007, and October 7, 2008.

II. Previous Restriction/Election Requirement

Applicants thank the Examiner for acknowledging Applicants' election of Group I, (claims 1-3 and 6-7 and further election of SEQ ID NOs: 5 and 6 of claim 3). *See* Page 2, Office Action of February 2, 2009. However, Applicants respectfully note that in Response of November 4, 2008, Applicants have elected a DNA and amino acid combination from the SEQ ID NOs: 3 and 4 as drawn to flab, not SEQ ID NOs: 5 and 6. Accordingly, Applicants respectfully request the Examiner's correction.

Applicants thank the Examiner for withdrawing the Requirement of species election and examine all species, i.e., Species A flagellins and Species B of adjuvant. *See* Page 3, Office Action of February 2, 2009.

III. Further Restriction/Election Requirement

A. At page 3 of Office Action, the Examiner alleges that, although Applicant has elected SEQ ID NOs: 5 and 6, the sequences read on patentably distinct sequences. Specifically, the Examiner asserts that DNA SEQ ID NO: 5 and amino acid SEQ ID NO: 6 are structurally

different and that each sequence is patentably distinct. The Examiner has withdrawn SEQ ID NO: 5.

Initially, Applicants respectfully note that in Response of November 4, 2008, Applicants have elected a DNA and amino acid combination from the SEQ ID NOs: 3 and 4 as drawn to flab, not SEQ ID NOs: 5 and 6. Applicants respectfully request the Examiner's clarification.

Nonetheless, the Examiner appears to assert that DNA SEQ ID NO: 3 and amino acid SEQ ID NO: 4 are structurally different and that each sequence is patentably distinct, which results in restriction. Thus, to advance the prosecution, Applicants respond as follows.

In response to the above Restriction Requirement, Applicants reiterate their election of amino acid SEQ ID NO: 4. Applicants, however, respectfully traverse because the Examiner appears to be using a wrong standard.

As grounds for the restriction, the Examiner states that DNA and amino acid sequences are structurally different and that each sequence is patentably distinct. However, Applicants submit that the instant application is a U.S. National Stage Application, which is not subject to the patentably distinct standard in accordance with 37 C.F.R. 1.141-1.146. M.P.E.P. § 1896 (IV). Instead, present application is subject to the unity of invention practice in accordance with 37 C.F.R. § 1.145 and 1.499 (effective May 1, 1993), and the DNA and amino acid sequences share the special technical feature of flaB under the unity of invention. Furthermore, as will be discussed below, the above special technical feature contributes over the prior art. The International Search and Preliminary Examination Guidelines, Chapter 10, 10.59, Example 39; M.P.E.P. § 1850.

Accordingly, Applicants respectfully request that this Restriction Requirement be reconsidered and withdrawn.

Applicants reserve the right to file a Divisional Application directed to non-elected subject matter.

B. At pages 3-4 of Office Action, the Examiner asserts that Claim 6 is drawn to mucosal vaccine adjuvant which is an independent/patentably distinct product and must be placed in an independent group. The Examiner reconsidered the grouping of the invention as follows:

Group I claims 1-3 and 7 drawn to a mucosal vaccine adjuvants comprising bacterial flagellins as an active component;

Group II claims 4-5 drawn to a method of manufacturing immunogen having adjuvanticity by flagellin; and

Group III claim 6 drawn to mucosal vaccine adjuvants comprising immunogens.

The Examiner has withdrawn Claims 4-6 as being drawn to a nonelected species Group II.

In response, Applicants acknowledges the Examiner's further Restriction Requirement and elect Group I (claims 1-3 and 7) without traversal.

Applicants reserve the right to file a Divisional Application directed to non-elected subject matter.

IV. Claim 7 Complies With 35 U.S.C. § 112

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. Specifically, the Examiner asserts that the phrase "so on" recited in Claim 7 renders the claim unclear whether the limitations following the phrase are part of the claimed invention.

In Response, Applicants have amended claim 7 to delete the phrase "so on."

Accordingly, Applicants respectfully request that the above indefiniteness rejection be reconsidered and withdrawn.

V. Claims 1-2 and 7 Are Patentable Over Wu

Claims 1-2 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu *et al.* (Proc. Nat. Acad. Science USA Vol. 86 pgs. 4726-4730, 1989; "Wu").

The Examiner appears to allege that Wu discloses mucosal vaccine adjuvants comprising bacterial flagellins as an active component, wherein flagellins are originated from Salmonella typhimurium, wherein vaccine adjuvants are for recombinant protein vaccine. Pages 4726 (column 2, last paragraph), 4727, 4729, and Figure 2-4.

Applicants respectfully disagree for the following reasons.

As pointed out in MPEP § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim." Thus, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. Of California*, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987)." Applicants respectfully assert that the Office Action failed to provide a prior art reference that teaches every element as set forth in the claim.

Independent claim 1 recites "[m]ucosal vaccine adjuvants comprising isolated bacterial flagellins as an active component." Applicants respectfully assert that Wu fails to disclose the mucosal vaccine adjuvant as set forth in independent claim 1.

Specifically, Wu discloses producing Salmonella expressed with a viral antigen outside the cell by inserting viral antigen into the variable region of flagellin, confirming the antibody formation against the viral antigen of Salmonella, and then testing an applicability of Salmonella

strain as a live vaccine. Pages 4727-4729. Here, Wu's vaccine activates the mucosal immune system by delivery of hepatitis viral antigen to the mucosal compartment. Page 4730, right column, 2nd paragraph. Thus, a strain of Salmonella with a viral antigen expressed on the surface of the Salmonella cell is used as an adjuvant. Wu's adjuvant does not comprise any isolated flagellin.

In fact, in Wu, the flagellin is used only as an instrument to express viral antigen on the surface of Salmonella cell. Pages 4727-4729.

On the other hand, the present invention discloses a mucosal vaccine adjuvant comprising isolated bacterial flagellins acting as a TLR-5 agonist. Figures 7-8 and Example 3.

Accordingly, Applicants respectfully assert that Wu fails to disclose "[m]ucosal vaccine adjuvants comprising isolated bacterial flagellins as an active component" as required by independent claim 1.

In addition, Applicants respectfully assert that dependent claims 2 and 7 are allowable over Wu at least because of the dependency from independent claim 1 and the reasons set forth above.

For the reasons set forth above, Applicants respectfully request that the above anticipation rejection be reconsidered and withdrawn.

VI. Claim 3 Depends From Allowable Claim 1

Claim 3 is objected to as being dependent upon rejected claim 1. The Examiner states that claim 3 is allowable with elected sequence subject matter of SEQ ID NO: 6.

Initially, Applicants respectfully note that in Response of November 4, 2008, Applicants have elected a DNA and amino acid combination from the SEQ ID NOs: 3 and 4 as drawn to flab, not SEQ ID NOs: 5 and 6. Applicants respectfully request the Examiner's clarification.

Nonetheless, Applicants respectfully assert that dependent claim 3 is allowable because independent claim 1 defines allowable subject matter for the reasons set forth above.

Accordingly, Applicants respectfully request that the above objection to claim 3 be reconsidered and withdrawn.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Sunhee Lee/

Sunhee Lee
Registration No. 53,892

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

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